HRP-013 | 07/22/2025 | Author: T. Bechert | Approver: A. Boutros

SOP: LARs, Children, and Guardians

1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:

1.1.1 Legally Authorized Representative (LAR)

1.1.2 Children

1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

- Double underlined "Children" as defined term (throughout Toolkit).
- Moved definition of "children" from under 3.1 (adults unable to consent) to (children).
- Removed guardian sub-bullet since term is now defined in HRP-001-SOP -Definitions.

3 POLICY

3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR.

3.1.1 When research is conducted in RI the following individuals meet this definition:

3.1.1.1 A “legally authorized representative” means "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research."

3.1.2 For research outside RI, a determination of who is a LAR is to be made with consultation from legal counsel.

3.2 DHHS and FDA’s Subpart D applies to all research involving children.

3.2.1 When research is conducted in RI all individuals under the age of 18 years are children. Exceptions exist for EXCEPTIONS. Contact legal counsel for more information.

3.2.2 For research outside RI, a determination of who is a child is to be made with consultation from legal counsel.

3.3 Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents or guardian.

3.3.1 Before obtaining permission from an individual who is not a parent, contact legal counsel.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

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7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.402

7.2 21 CFR §50.3

7.3 AAHRPP elements I.1.G, I-9, II.4.B

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